REMARKS

This responds to the Office Action mailed on July 28, 2008.

Claims 62 and 63 are added. Claims 5-7 are cancelled without prejudice as a result of the restriction requirement. Accordingly, claims 1-4, 8-63 are now pending. However, the Examiner has withdrawn claims 11, 18, 19, 21, 22, 29, 30, 34, 35, 37-39 and 41-61 from consideration. Applicant acknowledges that claim 63 does not fall within the elected invention. Accordingly, claims 1-4, 8-10, 12-17, 20, 23-28, 31, 32, 33, 36, 40 and 62 are now under consideration.

Support for the subject matter of new claim 62 is present throughout the specification, for example, at page 1, line 29 to page 2, line 6, in the Examples and at page 32, line 3 to page 33, line 8.

Support for the subject matter of new claim 63 is also present throughout the specification, for example, in claim 5, at page 3, lines 5-21 and in Examples III and IV.

Claims 1, 2, 8, 32 and 33 have been amended to comply with the restriction requirement by directing these claims to the elected invention.

The term "further" has been added to claim 31 to clarify that the media further comprises glutamate.

Applicant submits that these changes do not add new matter to the application.

Restriction Requirement

Applicant acknowledges the Examiner's comments and has cancelled claims 5-7 to comply with the restriction requirement. Applicant reserves the right to file divisional application(s) on the non-elected claims and/or species.

Section 103 Rejection

Claims 1-10, 12-17, 20, 23-28, 31, 32, 33, 36 and 40 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over combined teachings from Feldstine et al. (U.S. Patent 6,379,918; "Feldstine") in view of Bochner (U.S. Patent 6,136,554; "Bochner").

Claim 1 is directed to a method comprising: incubating a first sample suspected

of containing one or more competitor microbes and one or more pathogenic *Escherichia coli* in an acidic medium to produce a second sample; wherein incubating the first sample in the acidic medium generates a second sample that has a higher percentage of pathogenic *Escherichia coli* than the first sample.

Applicant submits that the combination of Feldstine and Bochner fails to disclose key elements of Applicant's claimed invention.. As explained in Applicant's specification, incubation of test samples unexpectedly selects against non-pathogenic microbes and selects for pathogenic microbes.

> An unexpected discovery of the inventive method is that competitive or non-pathogenic microbes may be selected against by incubation in an acidic medium in the absence of additional selective agents, such as antibiotics. Also, target microbes such as pathogenic bacteria, may be positively selected by incubation in an acidic medium.
> Applicant's specification at page 10.

However, the combination of Feldstine and Bochner utterly fails to disclose or teach a method that involves incubating the first sample in the acidic medium to generate a second sample that has a higher percentage of pathogenic *Escherichia coli* than the first sample.

Instead, Feldstine is limited to disclosure of a method for detecting a microorganism by contacting a test sample with a general enrichment media and detecting the microorganism by immunological reactivity of a highly conserved antigen epitopes with a reagent system comprised of an antibody linked to a detecting reagent. *See* Feldstine, Abstract and Summary of the Invention. Feldstine contemplates use of at least one structure modifying organic chemical in the general enrichment media but the structure modifying chemical is not an acid – instead it is a compound such as 2,4 dinitrophenol (Feldstine claim 1).

Hence, Feldstine utterly fails to disclose methods that involve incubation of a sample in an acidic medium. In fact, Feldstine mentions the term "acid" just once, in the Background of the Invention, as follows.

> Although, aggressive treatments are available which will

> expose interior antigen epitopes, these treatments destroy cell viability and in many cases disrupt cellular integrity completely. Examples of such treatments are heat treatment (boiling or autoclaving) and chemical extraction (nitrous *acid* digestion). *The significant shortcoming of these extractions is that they result in death of the microorganism.* Therefore, if the cell population had not reached a sufficiently detectable level prior to inactivation, *a negative determination will result.* Feldstine, col. 3, lines 31-41 (emphasis added).

Therefore, this disclosure clearly teaches that acidic treatment of microorganisms results in death of the microorganisms, which destroys the microorganisms and gives rise to a negative determination. As described in Applicant's specification and claims, enrichment of the target microbe to be detected is necessary to permit detection (see, e.g., Applicant's specification at pages 9-10). Such enrichment means that the target microbe(s) must survive and grow so that further tests (i.e., detection) can be performed. Accordingly, one of skill in the art would be discouraged by the teachings of Feldstine from using acid in any selection or enrichment procedure designed to ultimately detect target microbes such as pathogenic *Escherichia coli.*

Bochner fails to cure the defects of Feldstine. In particular, Bochner fails to disclose or teach that a culture media with an acidic pH should be used. Instead, Bochner relies upon sodium propionate and chromogenic compounds to identify some bacterial pathogens. While Bochner mentions propionic acid, Bochner specifically states that "all acidic carbon sources were adjusted to pH 6-8, prior to their addition to the media formulations." Bochner at col. 38, lines 26-28.

Moreover, Bochner fails to demonstrate that propionic *acid* is a selective agent. Instead, Bochner discloses that sodium propionate, which is not an acid, has some useful properties.

> A basal medium was prepared which contained agar (15 g/l), CE90 MX (5 g/l), Na_2 SO_4 (2.5 g/l), $MgSO_4$ (0.6 g/l), $MnSO_4$ (50 mg/l), D-sorbitol (10 g/l), D-arabitol (10 g/l), and Bluo-gal (300 mg/l). This medium was divided into nine batches. With the exception of batch #1, each batch contained one or more additional ingredients, which it was thought might stimulate growth and/or the coloration

> of E. coli 0157:H7.
>
> Batch #2 contained L-tryptophan (1 g/l); batch #3 contained ***sodium propionate*** (1 g/l); batch #4 contained sodium cyanate (200 mg/l); batch #5 contained tryptophan (1 g/l) and ***sodium propionate*** (1 g/l); batch #6 contained L-tryptophan (1 g/l) and sodium cyanate (200 mg/l); batch #7 contained ***sodium propionate*** (1 g/l) and sodium cyanate (200 mg/l); batch #8 contained tryptophan (1 g/l), ***sodium propionate*** (1 g/l), and sodium cyanate (200 mg/l); and batch #9 contained L-tryptophan (1 g/l), ***sodium propionate*** (1 g/l), and sodium cyanate (300 mg/l). These media were microwaved and dispensed as described in Example 1.
>
> Plates from each batch were streaked with various organisms listed in Table 6, including E. coli (ATCC #11775), E. coli 0157:H7...
>
> Of the formulations tested, batches #4, 8, and 9 permitted the best discrimination between E. coli 0157:H7 and other organisms...
>
> The ***propionate*** in batch #3 was found to inhibit the growth of E. agglomerans biogroup 4, E. amnigenus, and E. carotovora ss carotovora, which was very beneficial in improving the specificity of this medium for E. coli 0157:H7.
>
> Bochner, Example 4.

Nowhere does Bochner disclose or teach that an acidic medium can or should be used to select for pathogenic *Escherichia coli*.

Therefore, when the teachings of Feldstine are combined with those of Bochner, one of skill in the art would understand that acidic media should not be used when selecting for pathogenic microbes. Instead, the skilled artisan would recognize that Feldstine teaches away from using an acidic medium and would follow the teachings of Bochner that the media should be adjusted to pH 6-8.

In view of the fact that Feldstine teaches away from the invention, and Bochner specifically advocates use of ingredients a pH 6-8, Applicant submits that the rejection of claims 1-10, 12-17, 20, 23-28, 31, 32, 33, 36 and 40 under 35 U.S.C. § 103(a) over the combined teachings from Feldstine and Bochner should be withdrawn.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (516) 795-6820 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

MICHAEL GRANT

By his Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(516) 795-6820

Date October 28, 2008 By /Robin A. Chadwick/

Robin A. Chadwick
Reg. No. 36,477

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexendria, VA 22313-1450 on this 28th day of October 2008.

CANDIS BUENDING
Name

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